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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,154	12/31/2003	David Siever	49425	6977

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EXAMINER

BUSTAMANTE, ERIK J

ART UNIT PAPER NUMBER

3766

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,154

Applicant(s)

SIEVER, DAVID

Examiner

Erik J. Bustamante

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 31 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003, 6/10/2004, 7/19/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/10/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

Acknowledgment is made of applicant's Declaration, which was received by the Office on December 31, 2003.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/23/2005 is in compliance of 37 CFR 1.97. All the references cited are in compliance with the provisions of 37 CFR 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

1. The drawings were received on 6/10/2004. These drawings are objected to.
2. The drawings were received on 7/19/2004. These drawings are objected to.
3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the method of stimulating the central nervous system must be shown or the feature(s) canceled from the claim(s). While providing figures that prove claimed inventions works is acceptable, the applicant is advised that the aforementioned figures alone will not suffice for fulfilling the applicant's duty under 37 CFR 1.83(a). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure

number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 15, the applicant does not clearly state whether the stimulation frequencies refer to the auditory or visual stimulus.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

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and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 9 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 & 15 of U.S. Patent No. 5,709,645.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims teach a photic stimulation process wherein the frequencies that the right and left visual fields are stimulated differ by approximately .1 - 3Hz.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 14 is rejected under 35 U.S.C. 102(b) as anticipated by SIEVER (5,709,645).

Regarding claim 14, SIEVER discloses photic stimulation process comprising (Col 6 lines 20-24): (a) stimulating alpha frequencies in a range of from 8 to 12Hz in the right brain hemisphere (Table 1 & Col 5 lines 11-16) and (b) stimulating beta frequencies in a range of from 15 to 20 Hz in the left brain hemisphere (Table 1 & Col 5 lines 11-16) for relieving symptoms of depression.

7. Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by YASUSHI (5,241,967).

Regarding claim 6, YASUSHI discloses a process comprising: (a) obtaining a frequency of brain waves in a brain (Col 5 Lines 66-67 & Col 6 lines 1-6); and (b) stimulating the brain at a desired frequency (Col 6 Lines 7-19). While YASUSHI does not specifically mention the detection of aberrant brain waves, the process disclosed by YASUSHI is capable of detecting the aberrant frequencies. In addition, YASUSHI states that the said process responds to changes in the physiological state of the user, therefore one of ordinary skill in the art would realize that the process of YASUSHI is capable of detecting to an abnormal brain rhythm and responding to it. YASUSHI also does not specifically mention that the stimulus light should be approximately twice the aberrant frequency; however, YASUSHI's process is disclosed as being capable of stimulating at

twice the frequency of an aberrant wave (Col 7 lines 45-51). Furthermore, a final object of the process of YASUSHI is that once the user has been exposed to the stimulus that the brain waves of the user will mostly be kept at a frequency consistent with the stimulus light and that abnormal rhythms will be mostly suppressed (Col 7 lines 1-6).

Regarding claim 7, YASUSHI discloses a process according to claim 6 wherein the frequency of stimulation in step (b) is approximately 20 Hz based on the aberrant brain wave frequency in the brain being approximately 10 Hz for seasonal affective disorder (SAD) (Col 6 Lines 7-19 & Col 7 Lines 45-51).

Regarding claim 8, YASUSHI discloses a process according to claim 6 wherein the frequency of stimulation in step (b) is between approximately 14 to 18 Hz based on the aberrant brain wave frequency in the brain being approximately 7 to 9 Hz for fibromyalgia syndrome (FMS) (Col 6 Lines 7-19 & Col 7 Lines 45-51).

8. Claims 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by GORGES (4,315,502).

Regarding claim 9, GORGES shows a process for dissociating a subject from self awareness comprising: (a) stimulating a left brain hemisphere at a first frequency using photic stimulation and (b) simultaneously stimulating a right brain hemisphere at a second frequency using photic stimulation (Col 2 lines 26-32), wherein the first frequency differs from the second frequency by between approximately 0.1Hz and 3 Hz (Col 2 lines 40-46). While, GORGES does not implicitly state that the left and right hemispheres need to be stimulated at

different frequencies, it is an inherent feature that the left and right hemisphere can be stimulated at that frequency.

Regarding claim 10, GORGES shows a process according to claim 9, wherein the process is alternated with stimulating the left brain hemisphere and the right brain hemisphere at a low beta frequency in a range of from 12 to 15 Hz (Col 2 lines 40-46).

Regarding claim 11, GORGES shows a process according to claim 9, wherein the process is alternated with stimulating the left brain hemisphere and the right brain hemisphere at low-alpha or theta frequencies in a range of from 5 to 9 Hz. (Col 2 lines 40-46).

Regarding claim 12, GORGES shows a process according to claim 9, wherein the process is alternated with stimulating the left brain hemisphere and the right brain hemisphere at a delta frequency in a range of from 0 to 4 Hz (Col 2 lines 40-46 & Col 7 lines 13-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHUPRIKOV et al (5,137,018) in view of YOON (6,875,167 B2).

Regarding claim 1, CHUPRIKOV discloses a method of stimulating the left hemisphere of the brain and the right hemisphere of the brain by exposing the right halves of both eyes of a patient to light at one wavelength of light and exposing the left halves of both eyes to light at a different wavelength (Col 5 lines 1-34 & Col 14 lines 40-57). CHUPRIKOV also discloses that before that step that the both halves of each eye are exposed to a different wavelength (Col 5 lines 36-56 & Col 12 lines 48-55). Finally CHUPRIKOV shows that the steps can be repeated (Claim 1 (e)). CHUPRIKOV discloses also that the left hemisphere is stimulated when the right visual fields are stimulated and that the right hemisphere is stimulated when the left visual fields are stimulated (Col 12 lines 6-11). CHUPRIKOV does not disclose though that the left and right hemispheres are stimulated at the frequencies mentioned by the applicant, CHUPRIKOV only states the wavelength at which the stimulus light is set.

YOON teaches that brain wave frequencies of human brains tend to equilibrate around the same frequency of an external stimulus by the frequency following response (Col 1 lines 38-48). Implicit in this definition is that if one were to

expose a stimulus light of beta, low beta, and alpha frequencies to a subject that the brain would be stimulated at approximately the same frequency.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used stimulus light with beta, low beta, and alpha frequencies in the process of CHUPRIKOV instead of the wavelengths stated by CHUPRIKOV, in light of the teachings of YOON, to stimulate the left and right hemispheres at a beta, low beta, or alpha frequency.

Regarding claim 2, CHUPRIKOV implies in his disclosure that the period of time for the first stimulation portion is equal to the period for the second stimulation portion of the process (Col 5 lines 31-34 & lines 57-60).

Regarding claim 3, CHUPRIKOV discloses that the period of time in which the light stimulation is given to a patient should be in the range of time of 2-10 minutes (Col 2 lines 20-21 & Col 11 lines 22-23).

With respect to claim 4 & 5, CHUPRIKOV discloses the claimed invention except that the shifts between the first stimulation portion and the second stimulation portion should be sudden and take 30 seconds or be ramped in .1 Hz increments and take at least three minutes. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the shift between the first and second stimulation portions be either sudden and take 30

seconds or be ramped in .1 Hz increments and take at least three minutes, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

10. Claims 13,15-17 rejected under 35 U.S.C. 103(a) as being unpatentable over GORGES.

Regarding claim 13, GORGES discloses the claimed invention except that the process is carried out from 3 to 20 weeks. It would have been obvious to one having ordinary skill in the art at the time the invention was made to carry out the treatment process of claim 10 be carried from 3 to 20 weeks, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Allen*, 105 USPQ 233.

Regarding claim 15, GORGES discloses a photic and auditory stimulation method for pacing breathing in a subject to a predetermined breathing rate in the range of from 5 to 7 breath cycles per minute, the process comprising: (a) exposing the subject to an auditory cue (Col 2 Lines 24-25); and (b) simultaneously exposing the subject to various stimulation frequencies or combinations of frequencies (Col 2 lines 40-46). While GORGES does not specifically state that the method is used for pacing breathing, GORGES discloses that the method is used to relax a patient, which would imply an

alteration into the breathing rate of an individual. Furthermore, GORGES states that various areas of the brain can be stimulated with the disclosed process (Col 7 lines 31-32). One of ordinary skill in the art would recognize that using the aforementioned process one could stimulate the medulla oblongata, the portion of the brain that controls breathing rate, which has been established by scientific research, at a rate that would stimulate a breathing rate of 5-7 cycles per minute by routine trial and error.

Regarding claim 16, GORGES discloses a method according to claim 15 wherein the auditory cue is a synthesized heart beat sound (Col 3 lines 3-7).

Regarding claim 17, GORGES discloses a method according to claim 15, wherein the auditory cue is can be provided at from two to four times the predetermined breathing rate (Col 3 lines 3-7).

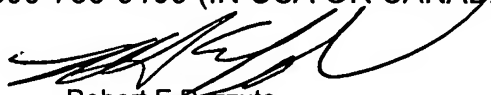
Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. (5,562,719; 3,893,450; 4,777,937; 6,488,698 B1; 5,306,228; 5,954,629; 5,219,322).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erik J. Bustamante whose telephone number is 571-272-8820. The examiner can normally be reached on Mon-Fri (7:30 - 11:30 AM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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